

REMARKS

The Official Action of January 12, 2010, and the prior art relied upon therein have been carefully reviewed. The claims in the application are now claims 14, 17-21, 24-29, 32-34 and 36-38, as well as new claim 41. These claims recite novel and unobvious subject matter, and also meet all other requirements for patentability including those of §112. Favorable reconsideration and allowance are respectfully requested.

New claim 41 has been added. It is patentable for the same reasons as the other claims, as pointed out below, at least for the reason that it depends from and incorporates the subject matter of claim 14 which is patentable for the reasons of record and the additional reasons set forth below. Support for new claim 41 is found in example 2 which refers to projectile bleeding, and also at page 3, line 13 which refers to arterial bleeding.

Claim 36 has also been amended to incorporate the dependant part of claim 39, so that in effect claim 36 as amended above corresponds to claim 39 rewritten in independent form.

Claims 14, 17-21, 24-29, 32-34 and 36-39 have been rejected under the first paragraph of §112 as failing to comply with the written description requirement with respect to the recitation of “needle-punched fabric” on the PTO’s position that the recitation of “needle-punched fabric” does not have proper support in the specification, thus introduces prohibited new matter, and consequently the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is respectfully traversed.

It was pointed out on page 8 of the amendment filed November 13, 2009, namely the first page of the Remarks section, that example 1 actually used such a “needle-punched” fabric. It is true that the specification does not explicitly say that the fabric there used was needle punched, but it does identify the non-woven fabric in question as one which is commercially available and sold under the trademark “NEOVEIL” by Gunze Limited. Thus, as a matter of **fact**, the non-woven fabric actually used and mentioned in the present specification in

example 1 was needle-punched. Therefore, it cannot be validly stated that the Applicants did not have possession of the use of such a fabric at the time the present application was filed.

In the bottom paragraph on page 4 of the Office Action, the PTO concludes, based on the translation which Applicants provided of Japanese Patent Publication 18579/1993 that NEOVEIL is not necessarily “needle punched,” and therefore Applicants’ fabric is not inherently needle-punched. Applicants do not understand how the PTO reaches this conclusion. NEOVEIL is a non-woven fabric and it is needle punched, and therefore Applicants’ specification inherently discloses the use of such a needle punched, non-woven fabric.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 14, 17-21, 24-29, 32-34 and 36-39 have been rejected as obvious from Sugitachi in view of newly cited and applied Koyfman et al USP 5,393,594 (Koyfman). This rejection is respectfully traversed.

As noted previously, Sugitachi in general provides a huge basket or shotgun disclosure which includes, among many other possibilities, the provision of a non-woven fabric which could be formed of polyglycolic acid, containing Factor XIII for wound healing (col. 1, lines 6 and 7, lines 32-34; and col. 3, lines 42-43). The rejection points to examples 2 and 6.

Example 2 used surgical gauze as the substrate, and this is clearly inconsistent with the present invention. Example 6 used a gelatin sponge and this also is clearly inconsistent with the present invention. These examples do not lead the person of ordinary skill in the art to or toward the present invention.

Before returning to the basket or shotgun disclosure of Sugitachi, Applicants respectfully note examples 7 and 8 of Sugitachi which disclose the use of a braided suture of polyglycolic acid. In example 7, the braided suture of polyglycolic acid was treated in accordance with example 5: as understood, this means that the absorbable braided suture of polyglycolic acid was dipped in an aqueous solution of Factor XIII and then lyophilized for twenty hours.

In example 8, the braided suture of polyglycolic acid was treated as disclosed in example 6: as understood, this means that the braided suture of polyglycolic acid was dipped in a mixed solution of Factor XIII and thrombin and lyophilized for twenty hours.

Considering the closest possible examples of Sugitachi to the present invention, it is clear that Sugitachi does not disclose Applicants' claimed subject matter. The PTO apparently agrees, as no rejection has been imposed under 35 USC §102.

Returning then to the basket or shotgun disclosure of Sugitachi, it is clear that sets of options are piled upon other sets of options, and therefore Sugitachi provides a huge number of permutations and combinations which do not lead the person ordinary skill in the art to what the present Applicants have done.

Starting with the substrates mentioned at col. 1, lines 50 et seq., the substrates can be monofilaments, they can be fibrous assemblies such as cotton, paper, non-woven fabrics, woven fabrics and knitted fabrics. They can be films, they can be sponges, they can be surgical sutures, they can be absorbent pads, bandages, burn dressings and packings, etc. etc.

On top of this first selection, the materials must then be selected, and they may be selected from natural polymers and synthetic polymers (col. 1, line 66 through col. 3, line 17.) Again, there are a huge number of possibilities.

However, at col. 3, lines 8-17, Sugitachi sets forth a smaller listing of preferred materials, including polyglycolic acid. But even among this preferred and smaller listing, there are still 18 specific and generic possibilities, which again does not lead the person of ordinary skill in the art to or towards the present invention. There are just too many options, with no specific guidance in the direction of the present invention.

The situation is similar to the situation faced by someone who wants to open a combination safe or a combination lock without knowing the combination. All the numbers are there, but how to put them together is unknown. The skilled artisan, looking at Sugitachi, has all the possibilities, but does not know which ones to select, and Sugitachi does not provide information which would lead to the present invention.

Moreover, and to take Sugitachi even farther from the present invention, it is to be noted (as already mentioned above) that Sugitachi is based on the use of Factor XIII, not

thrombin and fibrinogen in the same substrate. It is true that thrombin may be included with Factor XIII in Sugitachi, but Sugitachi does not teach the use of thrombin together with fibrinogen. Returning to examples 2 and 6 relied upon by the PTO, the surgical gauze of example 2 was treated with a mixture of Factor XIII and thrombin, and the same mixture was used in example 6.

Recognizing certain deficiencies of Sugitachi, the PTO relies on Greenawalt and Koyfman to allegedly make up for such deficiencies and lead the person of ordinary skill in the art to or toward the present invention. Thus, as understood, Greenawalt is relied upon to teach applying both fibrinogen and thrombin on the same substrate; and Koyfman is relied upon simply to show that it was known to provide non-woven fabric made by needle punching, which of course Applicants have never denied. The issue with respect of Koyfman is not whether needle punched non-woven fabrics were known, but whether it would have been obvious to use such a substrate in the environment of the present invention. Applicants respectfully submit that there is nothing in the prior art which would have made it obvious to substitute such a substrate for the types of substrates used in Sugitachi.

As regards Greenawalt, the Office Action focuses on Greenawalt's description of what was known prior to Greenawalt. But here is what Greenawalt states regarding that prior art (Greenawalt col. 1, lines 38 *et seq.*):

The major disadvantage of these preparations is that the water-like fluidity of the components renders them difficult to handle and administer. Although various efforts have been made to facilitate the administration of these compositions, ..., the basic problem of low viscosity remains.

Greenawalt thus teaches away from the TisseelTM system relied upon in the rejection. It cannot have been obvious for a person of ordinary skill in the art to have abstracted something from Greenawalt for incorporation into Sugitachi which Greenawalt indicates is disadvantageous.

Even if the proposed combination were obvious, contrary to Applicants' position as expressed above, the present invention as claimed would still define non-obvious subject matter by virtue of the fact that the prior art provides no reasonable expectation of the effects produced according to the present invention as shown in Tables 1 and 2 of Applicants'

specification. As the prior art provides no such reasonable expectation, the claims define non-obvious subject matter.

At the bottom of page 6 of the Office Action, reference is made to MPEP 2112. However, Section 2112 does not apply because the claimed and prior art products are not identical and are not substantially identical, and this is implicit in the fact that the rejection is based on a combination of three references. Sugitachi alone provides no example which can be said to inherently possess the same properties as Applicants' haemostatic material, and inherency cannot be based on a basket or shotgun disclosure where there is absolutely no reasonable certainty of the same results in the many thousands of possibilities. Indeed, the comparative examples in Applicants' specification show that one cannot assume that the Sugitachi options all produce inherently the same results as the present invention, and it is respectfully noted that comparative examples in an applicant's specification are to be treated the same as if such examples were to be presented in an affidavit or declaration.

Withdrawal of the rejection is in order and is respectfully requested.

Claim 14 has been provisionally rejected on the basis of obviousness-type double patenting over claims 5 and 6 of copending Application No. 11/941,779. This provisional rejection is respectfully traversed.

First, any rejection on the basis of double patenting is premature because no claims have been allowed in either application. There can be no double patenting when there is not even any single patenting.

Second, Applicants do not see that everything recited in claim 14 of the present application either appears in or is obvious from claims 5 and 6 of the copending application.

Withdrawal of the rejection is in order and is respectfully requested.

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of Applicants' claims.

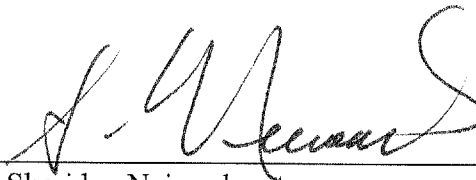
In re Appln of Takmori UCHIDA *et al*
Appln No. 10/542,577
Reply to Office Action of Jan. 12, 2010
Reply dated July 12, 2010

Applicants believe that all issues raised in the Official Action have been addressed above in a manner that should lead to patentability of the present application. Favorable reconsideration and allowance are respectfully requested.

If the Examiner has any questions or suggestions, the Examiner is respectfully requested to contact the undersigned at (202) 628-5197.

Respectfully submitted,

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